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L10: Entry 1 of 373

File: USPT

Dec 25, 2001

US-PAT-NO: 6333406

DOCUMENT-IDENTIFIER: US 6333406 B1

TITLE: Gene encoding protein antigens of Plasmodium falciparum and uses therefor

DATE-ISSUED: December 25, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Inselburg; Joseph W.	Hanover	NH	03755	
Bzik; David J.	Grantham	NH	03753	
Hori; Toshihiro	Toyonaka Osaka 560			JPX
Sugiyama; Tomohiko	Toyonaka Osaka 560			JPX

APPL-NO: 8/ 213419 [PALM]

DATE FILED: March 14, 1994

## PARENT-CASE:

RELATED APPLICATIONS This application is a continuation-in-part of U.S. application Ser. No. 07/870,806, filed Apr. 17, 1992 (abandoned) which is a continuation of U.S. application Ser. No. 07/231,771, filed Aug. 12, 1988 (abandoned). The contents of these applications are incorporated herein by reference.

INT-CL: [7] C07 H 21/02, C07 H 21/04, C12 N 15/30, A61 K 39/015

US-CL-ISSUED: 536/23.7; 424/191.1, 424/268.1, 424/272.1, 435/69.3, 435/69.7, 435/70.1, 435/71.1, 435/320.1, 435/455, 435/471, 435/325, 435/243, 514/44, 536/23.5

US-CL-CURRENT: 536/23.7; 424/191.1, 424/268.1, 424/272.1, 435/243, 435/320.1, 435/325, 435/455, 435/471, 435/69.3, 435/69.7, 435/70.1, 435/71.1, 536/23.5

FIELD-OF-SEARCH: 530/350, 530/387, 530/820, 530/806, 436/517, 514/2, 514/12, 514/44, 424/88, 424/191.1, 424/268.1, 424/272.1, 435/69.7, 435/71.1, 435/320.1, 435/455, 435/471, 435/325, 435/243, 435/69.3, 435/70.1, 536/23.5, 536/23.7

## PRIOR-ART-DISCLOSED:

## U. S. PATENT DOCUMENTS

 

PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
<input type="checkbox"/> <u>4735799</u>	April 1988	Patarroyo	424/88
<input type="checkbox"/> <u>4767622</u>	August 1988	Ristic et al.	424/88
<input type="checkbox"/> <u>4906564</u>	March 1990	Lyon et al.	435/7
<input type="checkbox"/> <u>4978621</u>	December 1990	Ardeshir et al.	435/243
<input type="checkbox"/> <u>5028425</u>	July 1991	Good et al.	424/88
<input type="checkbox"/> <u>5194587</u>	March 1993	Knapp et al.	530/324

## FOREIGN PATENT DOCUMENTS

FOREIGN-PAT-NO	PUBN-DATE	COUNTRY	US-CL
0 154 454	September 1985	EPX	
0 283 882	September 1988	EPX	
WO 87/00533	January 1987	WOX	
WO 87/03882	July 1987	WOX	

## OTHER PUBLICATIONS

Knapp et al., "Molecular Cloning, genomic structures and localization in a blood stage antigen of *Plasmodium falciparum* characterized by a serine stretch," *Molecular and Biochemical Parasitology*, 32(1989) 73-84.\*

Maniatis et al., *Molecular Cloning: A Laboratory Manual* (Cold Spring Harbor Laboratory 1982); Chapter 10, pp. 310-361.\*

Banyal, H.S. and J. Inselburg, "Isolation and Characterization of Parasite-Inhibitory *Plasmodium falciparum* Monoclonal Antibodies" *Am J. Trop. Med. Hyg.*, vol. 34, No. 6, pp. 1055-1064, 1985.

Bhatia, A. et al., "Immunochemical Analysis of a Major Antigen of *Plasmodium falciparum* (p126) Among Ten Geographic Isolates" *Am. J. Trop. Med. Hyg.*, vol. 36, No. 1, pp. 15-19, 1987.

Chulay, J.D. et al., "Monoclonal Antibody Characterization of *Plasmodium falciparum* Antigens in Immune Complexes Formed When Schizonts Rupture in the Presence of Immune Serum" *J. Immunology*, vol. 139, pp. 2768-2774, 1987.

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Horii, T. et al., "Characterization of antigen-expressing *Plasmodium falciparum* cDNA clones that are reactive with parasite inhibitory antibodies", *Mol. Biochem. Parasitol.*, vol. 30, pp. 9-18, 1988.

Inselburg, J. et al., "Protective Immunity in Aotus Monkeys by a Recombinant SERA Protein of *Plasmodium falciparum*: Adjuvant Effects on Induction of Protective Immunity" *Infection and Immunity*, vol. 61, No. 5, pp. 2041-2047, May 1993.

Inselburg, J. et al., "Protective Immunity Induced in Aotus Monkeys by a Recombinant SERA Protein of *Plasmodium falciparum*: Further Studies Using SERA 1 and MF75.2 Adjuvant" *Infection and Immunity*, vol. 61, No. 5, pp. 2048-2052, May 1993.

Inselburg, J. et al., "Protective Immunity in Aotus Monkeys by Recombinant SERA Proteins of *Plasmodium falciparum*" *Infection and Immunity*, vol. 59, No. 4, pp. 1247-1250, Apr. 1991.

Kemp, D.J. et al., "Expression of *Plasmodium falciparum* blood-stage antigens in *Escherichia coli*: Detection with antibodies from immune humans" *Proc. Natl. Acad. Sci. USA*, vol. 80, pp. 3787-3791, Jun. 1993.

Perrin, L.H. et al., "Antimalarial Immunity in Saimiri Monkeys: Immunization with Surface Components of Asexual Blood Stages" *J. Exp. Med.*, vol. 160, pp. 441-451, Aug. 1984.

Weber, J.L. et al., "Blood Stage Antigen Genes of *Plasmodium falciparum*" in *Molecular Strategies of Parasitic Invasion*, New York: Alan R. Liss, Inc., pp. 379-388, 1987, from the Proceedings of a MacArthur Foundation-UCLA Symposium, Utah, Jan. 26-31, 1987.

ART-UNIT: 161

PRIMARY-EXAMINER: Chin; Christopher L.

ASSISTANT-EXAMINER: Grun; James L.

ATTY-AGENT-FIRM: Lahive &amp; Cockfield, LLP DeConti, Jr, Esq.; Giulio A. Williams, Esq.; Megan E.

## ABSTRACT:

A *Plasmodium falciparum* gene encoding immunogenic SERA protein has been isolated by a) systematically screening a lambda gt11 recombinant DNA expression library with a murine monoclonal antibody directed against protein antigens of this pathogen, and b) systematically screening a lambda gt11 genomic cDNA and oligonucleotide probes directed against this pathogen. A 111 kDa protein has been shown to have immunogenic activity against parasite inhibitory antibodies. The gene encoding this protein, including the signal sequence and regulatory sequence in the adjacent 5' flanking sequence has been isolated and sequenced.

Isolation and characterization of genes encoding major protein antigens of *P. falciparum* make it possible to develop reagents useful in the diagnosis, prevention and treatment of malaria. In addition, the signal sequences or regulatory sequences of this gene can be used to stimulate the production of other useful genetic products.

13 Claims, 29 Drawing figures

From: Baskar, Padmavathi  
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1. Sim BK, Romans P, Harun S. Articles  
Use of chitinase to facilitate detection of protozoan, helminth and single copy genes in squashed whole mosquitoes.  
Mol Biochem Parasitol. 1989 May 1;34(2):127-34.
2. J.B.C 2000, 275:10331-10341
3. P.N.A.S 1999, 96:14061-14066
4. P.N.A.S 1993, 90:4266-4270
5. SCIENCE 1998, 282; 1126-1132

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Art Unit 1645  
Patent Examiner/Biotechnology  
CM-1, 8E-13  
703-308-8886

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1.

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MIC  
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